

## § 25.31b

upon compliance with current emissions requirements at the production site(s).

(ii) *Format item 7.* Discuss whether the use of the product can reasonably be expected on the basis of all available evidence to alter significantly the concentration and distribution of the product, its metabolites, degradation products, or its constituent parts in the environment.

(iii) *Format item 8.* Report existing data relating to the environmental effects of substances expected to be emitted into the environment as a consequence of use of the product. Report information obtained from the scientific literature on the toxicity of the product to laboratory animals, e.g., that information which is submitted to satisfy human safety requirements, and to organisms in the environment, e.g., fish, invertebrates, plants, fungi, and bacteria, that may be exposed to the product.

(6) For approval or issuance by the agency of a food or color additive petition, NDA, supplemental NDA, biological product license, NADA, or supplemental NADA for a product that has been approved by the Environmental Protection Agency (EPA) under section 4 or 5 of the Toxic Substances Control Act (TSCA) or under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the following information is required:

(i) *Format items 7 and 8.* To address these items, rely on environmental information in studies submitted to EPA, in the application/petition submitted for FDA approval, and in the scientific literature. Describe any potential adverse environmental impacts determined by EPA.

(ii) *Format item 15(b).* For studies submitted to EPA or for relevant studies submitted in the application/petition to meet the requirements of the Federal Food, Drug, and Cosmetic Act, test reports may include only a brief description and summary of results of

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each study in lieu of attaching complete test reports.

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[50 FR 16656, Apr. 26, 1985, as amended at 50 FR 30267, July 25, 1985; 60 FR 36594, July 17, 1995]

### § 25.31b Environmental assessment for withdrawals of approval and other restrictions—Format 2.

For proposed actions to withdraw approval or otherwise restrict or reduce the use of food or color additives, drugs, biological products, animal drugs, and class III medical devices, any environmental assessment prepared by the agency will be in the following format:

#### ENVIRONMENTAL ASSESSMENT

1. *Description of the proposed action:* Describe the proposed action, the regulatory authority for the proposed action, the underlying purpose of and need for the proposed action, and how the proposed action addresses the underlying purpose and need for action.

2. *Environmental consequences of the proposed action:* Describe the uses and the magnitude (production volume and/or sales) of such uses for the product(s) for which approval would be withdrawn or otherwise restricted or reduced and for the available substitute products. Determine those uses of the restricted product(s) for which no substitute products are available and the magnitude and essentiality of such uses. Discuss the environmental impacts of (1) reducing or eliminating environmental exposures to the restricted product; (2) natural resources and energy used in producing, distributing, using, and disposing of the restricted product compared with those required for the available substitute products; (3) any expected increased production and use of substitute products; and (4) essential uses of the restricted product for which there would be no substitutes.

3. *Mitigation measures:* Describe measures which would be taken to avoid or mitigate potential adverse environmental effects associated with the proposed action.

4. *Description of regulatory alternatives to the proposed action and the expected environmental consequences:* Describe in detail the environmental impact of reasonable alternatives to the proposed action (including no action),

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particularly those that will enhance the quality of the environment and avoid some or all of the adverse environmental effects of the proposed action.

5. *Comparative analysis of proposed action and alternatives:* Provide a comparative analysis of the environmental benefits and risks of the proposed action and alternatives. Identify the preferred action based on environmental factors.

6. *List of preparers:* Those persons preparing the assessment and their areas of expertise shall be presented. Persons and agencies consulted shall be listed.

7. *References:* List complete citations for all referenced material. Copies of referenced articles not generally available should be attached.

8. *Appendices:* Append detailed physical, chemical, biological, and environmental data on products that are the subject of the proposed action.

### §25.31c Environmental assessment format for extramural contracts, grants, or other research agreements—Format 3.

For extramural contracts, grants, or other research agreements subject to environmental assessment, the contractor or applicant shall use the following format:

#### ENVIRONMENTAL ASSESSMENT

1. *Date:*
2. *Name of prospective contractor/ applicant:*
3. *Address:*
4. *Description of the proposed research activities:* Briefly describe the purpose of the proposed research, the locations where the research activities would occur, and the types of environments present at those locations.
5. *Information on the chemical substances and infectious agents to be used:* Provide the information listed in Table 1 on each of the chemical substances and infectious agents to be used in the research activity, to the extent that they can be identified, either specifically or generically, and including such items as organic solvents as well as the chemicals of major research interest.

TABLE 1.—CHEMICAL SUBSTANCES/INFECTIOUS AGENTS TO BE USED IN THE PROPOSED RESEARCH ACTIVITIES

Chemical infectious agent name (complete scientific nomenclature)	Approximate amounts to be used <sup>a</sup>	Hazard code <sup>b</sup>	Emissions controls: (environmental and occupational) <sup>c</sup>
1. ....	.....	.....	.....
2. ....	.....	.....	.....
3. ....	.....	.....	.....

<sup>a</sup>Specify in metric units of mass or volume.

<sup>b</sup>I—infectious, C—carcinogenic, M—mutagenic, T—teratogenic, A—acutely toxic or poison, COR—corrosive, E—explosive or flammable, R—radioactive, O—other hazard, please specify, NH—nonhazardous.

<sup>c</sup>Examples include use of fume hoods, use of protective clothing/gear by laboratory personnel, chemical inactivation of wastes, separation of hazardous from nonhazardous wastes, and subsequent disposal by a firm licensed for this purpose.

6. *Compliance with Federal, State, and local environmental and occupational requirements.* Cite and include a statement of compliance with applicable emissions requirements (including occupational) at the Federal, State, and local level. Discuss the effect that the proposed research will have upon compliance with these requirements.

7. *List of preparers:* Those persons preparing the assessment together with their qualifications (expertise, experience, professional disciplines) shall be listed. Persons and agencies consulted shall also be listed.

8. *Certification:* The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the prospective contractor or applicant submitting the environmental assessment.

(Date) .....

(Signature of responsible official)

(Title) .....

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[50 FR 16656, Apr. 26, 1985, as amended at 50 FR 30267, July 25, 1985]

### §25.31d Environmental assessment for establishment of tolerances or action levels—Format 4.

For proposed actions to establish tolerances or action levels for unavoidable poisonous or deleterious substances in food for human or animal consumption or in packaging materials intended for use with human food and animal feed, the agency will prepare an environmental assessment in the following format:

#### ENVIRONMENTAL ASSESSMENT

1. *Description of the proposed action:* Describe the proposed action, the regulatory authority for the proposed action, the underlying purpose of and need for the proposed action, and how the proposed action addresses the underlying purpose and need for action.
2. *Environmental consequences of the proposed action:* Describe the potential environmental impacts of the proposed action including effects on natural resources and energy, effects on food production, effects on